

§ 164.400

45 CFR Subtitle A (10–1–10 Edition)

| Standards | Sections | Implementation Specifications (R)=Required, (A)=Addressable |
|--|---------------|--|
| Assigned Security Responsibility | 164.308(a)(2) | Sanction Policy (R) |
| Workforce Security | 164.308(a)(3) | Information System Activity Review (R) |
| | | (R) |
| | | Authorization and/or Supervision (A) |
| | | Workforce Clearance Procedure |
| | | Termination Procedures (A) |
| Information Access Management | 164.308(a)(4) | Isolating Health care Clearinghouse Function (R) |
| | | Access Authorization (A) |
| | | Access Establishment and Modification (A) |
| Security Awareness and Training | 164.308(a)(5) | Security Reminders (A) |
| | | Protection from Malicious Software (A) |
| | | Log-in Monitoring (A) |
| | | Password Management (A) |
| Security Incident Procedures | 164.308(a)(6) | Response and Reporting (R) |
| Contingency Plan | 164.308(a)(7) | Data Backup Plan (R) |
| | | Disaster Recovery Plan (R) |
| | | Emergency Mode Operation Plan (R) |
| | | Testing and Revision Procedure (A) |
| | | Applications and Data Criticality Analysis (A) |
| Evaluation | 164.308(a)(8) | (R) |
| Business Associate Contracts and Other Arrangement. | 164.308(b)(1) | Written Contract or Other Arrangement (R) |
| Physical Safeguards | | |
| Facility Access Controls | 164.310(a)(1) | Contingency Operations (A) |
| | | Facility Security Plan (A) |
| | | Access Control and Validation Procedures (A) |
| | | Maintenance Records (A) |
| Workstation Use | 164.310(b) | (R) |
| Workstation Security | 164.310(c) | (R) |
| Device and Media Controls | 164.310(d)(1) | Disposal (R) |
| | | Media Re-use (R) |
| | | Accountability (A) |
| | | Data Backup and Storage (A) |
| Technical Safeguards (see § 164.312) | | |
| Access Control | 164.312(a)(1) | Unique User Identification (R) |
| | | Emergency Access Procedure (R) |
| | | Automatic Logoff (A) |
| | | Encryption and Decryption (A) |
| Audit Controls | 164.312(b) | (R) |
| Integrity | 164.312(c)(1) | Mechanism to Authenticate Electronic Protected Health In- formation (A) |
| | | (R) |
| Person or Entity Authentication | 164.312(d) | Integrity Controls (A) |
| Transmission Security | 164.312(e)(1) | Encryption (A) |

**Subpart D—Notification in the
Case of Breach of Unsecured
Protected Health Information**

SOURCE: 74 FR 42767, Aug. 24, 2009, unless otherwise noted.

§ 164.400 Applicability.

The requirements of this subpart shall apply with respect to breaches of protected health information occurring on or after September 23, 2009.

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.

(1)(i) For purposes of this definition, *compromises the security or privacy of the protected health information* means poses a significant risk of financial, reputational, or other harm to the individual.

(ii) A use or disclosure of protected health information that does not include the identifiers listed at § 164.514(e)(2), date of birth, and zip code does not compromise the security or